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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,794	11/15/2000	Yannick Batard	A32000-A-072667.0172	4605

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BAKER BOTTS L.L.P.
30 ROCKEFELLER PLAZA
44TH FLOOR
NEW YORK, NY 10112-4498

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/25/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,794

Applicant(s)

BATARD ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-18 and 22-27 is/are rejected.
- 7) ☒ Claim(s) 14, 19-21 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply, filed December 20, 2002 as Paper No. 10, to the previous Office Action. Amendments were made to the claims in the previous response mailed August 19, 2002 as Paper No. 7.

Claims 1-28 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 5, mailed March 22, 2002, that is not addressed in this action has been withdrawn.

Priority

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/158,767, now US Patent No. 6,180,363, filed September 23, 1998." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Information Disclosure Statement

The information disclosure statement filed August 19, 2002 as Paper No. 8 has been considered, and a signed and initialed copy is attached to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 7-13 and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotula *et al.* (*Biotech.* 9:1386-1389, 1991; see entire document; henceforth Kotula). **This is a new rejection not necessitated by amendment.**

Kotula teaches a recombinant yeast cell comprising a non-yeast DNA (mouse IG Kappa gene), wherein the codon bias of the mouse gene is optimized for the expression of the gene in the yeast *S. cerevisiae* (see for example page 1386, right side, first full paragraph). Overall, 115 of 215 (53%) of the codons were replaced (necessarily indicating that at least one stretch of 10 consecutive codons had at least 2 or more codons replaced), some of which were in the 5' region of the gene, and the expression of the gene was found to increase 5-fold over that of the mouse cDNA sequence alone (see for example page 1386, right hand side). Since the gene as optimized contains DNA sequences that are not ordinarily part of the gene, the optimized gene is by definition a chimeric gene. The genes were cloned into the backbone of yeast expression vector pBR which contains regulatory and selection sequences that are operable in yeast (see for example the legend of Figure 1), therefore teaching a yeast expression vector. The protein was produced, therefore Kotula teaches a method of producing the protein with such a yeast cell (see for example Figure 3). As a result, Kotula anticipates each of the claims set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Kotula as applied above under 35 USC 102(b) in view of the "Codon Usage Database" at GenBank <http://www.kazusa.or.jp/codon> (see entire Web Page, IDS reference; henceforth the CUD). **This is a new rejection not necessitated by amendment.**

Kotula teaches the elements as set forth above in the rejection under 35 USC 102(b) as it regards codon optimization for the enhanced production of heterologous proteins in yeast.

Kotula does not teach what specific codons should be used for yeast, nor does it teach the relative frequencies of the codons in yeast.

CUD teaches the codon bias and relative frequencies for a vast number of organisms, including yeast (see for example the homepage of the aforementioned website). Furthermore, the website was present prior to the filing or priority date of the instant specification.

It would have been obvious to the ordinary skilled artisan to combine the teachings of Kotula with those of CUD to result in the claimed invention because the ordinary skilled artisan would want to be certain they were optimizing the codons to the fullest extent applicable for the

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particular yeast strain, therefore they would naturally consult the CUD which has accumulated such knowledge. The ordinary skilled artisan would have been motivated to combine the teachings with the expected benefit of knowing for certain that they had appropriately and fully optimized the coding sequence of the desired protein in order to produce a protein as efficiently as possible.

Absent evidence to the contrary and given the teachings of the stated prior art and the high level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotula as applied under 35 USC 102(b) in view of Neill *et al.* (cited in the previous Office Action; henceforth Neill; see entire document). **This is a new rejection not necessitated by amendment.**

Kotula teaches the elements as set forth above in the rejection under 35 USC 102(b) as it regards codon optimization for the enhanced production of heterologous proteins in yeast.

Kotula does not teach the codon optimization of a plant enzyme in the production of a recombinant yeast.

Neill teaches the production of wheat α -gliadin in yeast (see for example the abstract and page 313, section (e)). Neill further goes on to suggest that α -gliadin has a potential translation limitation in yeast due to the availability of a particular glutamine tRNA (see the last line of the

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Abstract). Potential uses of α -gliadin are as important constituents of doughs (see for example page 304, bridging paragraph for the left and right sides of the page).

It would have been obvious to the ordinary skilled artisan to combine the teachings of Kotula with those of Neill to result in the claimed invention because α -gliadin is a valuable product as taught in Neill whose overexpression is limited by codon availability in yeast, and Kotula teaches a method of overcoming the limitations of codon bias in yeast. The ordinary skilled artisan would have been motivated to combine the teachings with the expected benefit of increasing the expression and therefore production of α -gliadin, a valuable wheat protein as taught by Neill.

Absent evidence to the contrary and given the teachings of the stated prior art and the high level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claim 27 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent No. 6,180,363 (henceforth the '363 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 27 of the instant application describe a generic method of producing a polypeptide utilizing a recombinant cell that comprises a heterologous protein that has undergone codon optimization that is anticipated by the specific claim of the '363 patent which describes particular parameters regarding the codon usage in a specific gene. The generic claim of the instant application would necessarily encompass the specific limitations set forth in the claim of the '363 patent, therefore the specific claim anticipates the generic claim. **This is a new rejection not necessitated by amendment.**

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the patent. Also, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the US Patent No. 6,180,363, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

Allowable Subject Matter

Claims 14, 19-21 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

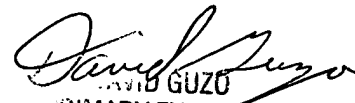
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
March 21, 2003


DAVID GUZO
PRIMARY EXAMINER